| | Application No. | Applicant(s) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------|
| Notice of Allowability | 10/789,865 | GRETZKE ET AL. |
| | Examiner | Art Unit |
| | Susannah Chung | 1626 |
| | Susamian Chung | 1020 |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. | | |
| 1. This communication is responsive to <u>01/30/2006</u> . | | |
| 2. The allowed claim(s) is/are <u>1-9,11,12,15 and 16</u> . | | |
| 3. Acknowledgment is made of a claim for foreign priority un a) All b) Some* c) None of the: 1. Certified copies of the priority documents have | | |
| 2. Certified copies of the priority documents have been received in Application No | | |
| 3. Copies of the certified copies of the priority documents have been received in this national stage application from the | | |
| International Bureau (PCT Rule 17.2(a)). | | |
| * Certified copies not received: | | |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. | | |
| 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. | | |
| 5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. | | |
| (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached | | |
| 1) hereto or 2) to Paper No./Mail Date | | |
| (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date | | |
| Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). | | |
| 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. | | |
| | | |
| Attachment(s) 1. ☑ Notice of References Cited (PTO-892) | 5. The Notice of Informal P | ratent Application (PTO-152) |
| 2. Notice of Draftperson's Patent Drawing Review (PTO-948) | 6. ☑ Interview Summary | ·· · · · · · · · · · · · · · · · · · · |
| 3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/0 | Paper No./Mail Da | te <u>031306</u> . |
| Paper No./Mail Date | | |
| Examiner's Comment Regarding Requirement for Deposit of Biological Material | | ent of Reasons for Allowance |
| - | 9. | |
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DETAILED ACTION

Claims 1-9 and 11-19 are pending in the instant application. Claim 10 has been canceled.

Response to Applicant's Remarks/Amendments

Applicant's remarks and amendment to the claims filed on 1/30/2006 are acknowledged.

Claims 1-4 stand rejected under 35 USC 112, 1st paragraph. This rejection is withdrawn in view of the amendment to the claims filed on 1/30/2006.

Claims 13-19 stand rejected under 35 U.S.C. 112, 1st paragraph, as failing to comply with the enablement requirement. The rejection of Claims 15 and 16 are withdrawn in view of the non-patent literature documents supporting the specific methods of treatment (i.e. diabetes mellitus and dyslipidemia) of utilizing the compounds listed in Claim 1. The rejection of Claims 13-14 and 17-19 stand as failing to comply with the enablement requirement under 35 U.S.C.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Barbara Kurys on 03/13/2006. The application has been amended as follows:

Delete Claims 13-14 and 17-19.

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Allowable Subject Matter

Claims 1-9,11-12, and 15-16 directed to compounds, compositions, and methods

of use of formula (I), , depicted in claim 1, wherein Ring A is (C6)-cycloalkanediyl; Ring B is as stated in the reply on page 2; R1, R2 are each independently H or (C1-C6)-alkyl; R3 is (C1-C6)-alkyl; X is as stated in the reply on page 2; Y is (C1-C6)-alkanediyl are allowable.

Reasons for Allowance

The present invention is directed to Cycloalkyl derivatives having bioisosteric carboxylic acid groups and their pharmaceutical compositions. The closest prior arts of record are U.S. Pat.

$$R^1 \longrightarrow X$$
 R^2
 R^2

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No. 5,468,762, which teach similar azolidinediones,

journal article by Malamas et al., titled "New Azolidinediones as Inhibitors of Protein Tyrosine Phophatase 1B with Antihyperglycemic Properties," J. Med. Chem., Vol. 43 (2000), pages 995-

$$R^{1}$$
 $(CH_{2})_{n-Q}$
 $(CH_{3})_{n-Q}$
 $(CH_{3})_{n-Q$

1010, especially page 996, Compound 15,

Instead of a C6-cycloalkyl group at Ring A of the instant application, the prior art has a benzene ring.

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Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098.

The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the

organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Chung

Patent Examiner, AU 1626

Date: 03/13/2006

KAMAL A. SAEED, PH.D.

PRIMARY EXAMINER

Canal Sacer